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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,004	04/12/2007	Henning Walczak	187104/US/BM	1454

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EXAMINER	
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ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,004	WALCZAK, HENNING	
	Examiner	Art Unit	
	JON M. LOCKARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-51* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 9-26, 33-38, and 40-44 (in part), in so far as they are drawn to CD95/Ig fusion proteins and nucleic acids encoding the same.

Group II, claim(s) 1-5, 9-23, 27-29, 33-38, 40-41, and 43-44 (in part), in so far as they are drawn to TRAIL receptor/Ig fusion proteins and nucleic acids encoding the same.

Group III, claim(s) 1-5, 9-23, 30-38, 40, and 44 (in part), in so far as they are drawn to TNF receptor/Ig fusion proteins and nucleic acids encoding the same.

Group IV, claim(s) 1-5, 9-23, 33-38, 40, and 44 (in part), in so far as they are drawn to VEGF receptor/Ig fusion proteins and nucleic acids encoding the same.

Group V, claim(s) 1-2, 6-23, 33-38, 40, and 44 (in part), in so far as they are drawn to CD95 ligand/Ig fusion proteins and nucleic acids encoding the same.

Group VI, claim(s) 1-2, 6-23, 33-38, 40, and 44 (in part), in so far as they are drawn to TRAIL/Ig fusion proteins and nucleic acids encoding the same.

Group VII, claim(s) 1-2, 6-23, 33-38, 40, and 44 (in part), in so far as they are drawn to TNF/Ig fusion proteins and nucleic acids encoding the same.

Group VIII, claim(s) 1-2, 6-23, 33-38, 40, and 44 (in part), in so far as they are drawn to VEGF/Ig fusion proteins and nucleic acids encoding the same.

Group IX, claim(s) 1-2, 6-23, 33-38, 40, and 44 (in part), in so far as they are drawn to IL-15/Ig fusion proteins and nucleic acids encoding the same.

Group X, claim(s) 39, drawn to transgenic organisms.

Group XI, claim(s) 45-47 and 50-51 (in part), in so far as they are drawn to fusion proteins comprising CD95 and an oligomerizing component.

Group XII, claim(s) 45-47 and 50-51 (in part), in so far as they are drawn to fusion proteins comprising a TRAIL receptor and an oligomerizing component.

Group XIII, claim(s) 45-47 and 50-51 (in part), in so far as they are drawn to fusion proteins comprising a TNF receptor and an oligomerizing component.

Group XIV, claim(s) 45 and 48-51 (in part), in so far as they are drawn to fusion proteins comprising a CD95 ligand and an oligomerizing component.

Group XV, claim(s) 45 and 48-51 (in part), in so far as they are drawn to fusion proteins comprising TRAIL and an oligomerizing component.

Group XVI, claim(s) 45 and 48-51 (in part), in so far as they are drawn to fusion proteins comprising TNF and an oligomerizing component.

2. The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Pursuant to 37 C.F.R. § 1.475(B-D), the ISA/US considers that where multiple products and/or processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto, i.e., method of making and a method of using. However, multiple products and/or multiple methods are not provided for in the rules. Accordingly, the main invention (Group I) comprises the first recited product, a TRAIL receptor/Ig fusion protein and a nucleic acid encoding the same. The products of Groups II-XVI are distinct from the first claimed product because the individual fusion proteins are structurally and functionally different compounds, having different amino acid sequences, structures and activities. Lack of unity is shown because these polypeptides lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility. Therefore, unity of invention is lacking.

Election of Species:

3. This application contains claims directed to more than one species of the generic invention. Specifically, the claims are directed to more than one species of TRAIL receptors.

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

human TRAIL receptor-1, human TRAIL receptor-2, human TRAIL receptor-3, and human TRAIL receptor-4.

4. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

5. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The claims are deemed to correspond to the species listed above in the following manner:

human TRAIL receptor-1, human TRAIL receptor-2, human TRAIL receptor-3, and human TRAIL receptor-4: claim 28.

The following claim(s) are generic: claim 27.

7. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the individual polypeptides are structurally and functionally different compounds, having different amino acid sequences, structures and activities. Lack of unity is shown because these polypeptides lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

8. This application contains claims directed to more than one species of the generic invention. Specifically, the claims are directed to more than one species of TNF receptors. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

human TNF receptor-1 and human TNF receptor-2.

9. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. The claims are deemed to correspond to the species listed above in the following manner:

human TNF receptor-1 and human TNF receptor-2: claim 31.

The following claim(s) are generic: claim 30.

12. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the individual polypeptides are structurally and functionally different compounds, having different amino acid sequences, structures and activities. Lack of unity is shown because these polypeptides lack a common utility which is

based upon a common structural feature which has been identified as the basis for that common utility.

13. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

14. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Manjunath N. Rao, Ph.D.**, can be reached on **(571) 272-0939**. The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jon M. Lockard, Ph.D.
September 22, 2009

/Jon M Lockard/
Examiner, Art Unit 1647